

ASX RELEASE

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PARADIGM'S PHASE 2 CLINICAL DATA - UPDATE

Highlights:

- Paradigm's phase 2b clinical trial in participants with knee osteoarthritis and concurrent bone marrow lesions is 50% recruited and remains ahead of schedule. **Expected read-out Q4 CY2018**
- Phase 2a, clinical trial in participants with viral arthralgia (Ross River virus) is currently over 70% recruited and scheduled to recruit further subjects following seasonal recurrence of the disease. **Expected read-out Q4 CY2018**
- In addition to the two current phase 2 clinical trials, doctors are currently treating 147 osteoarthritis patients via the TGA Special Access Scheme

Melbourne 27 March 2017 Paradigm Biopharmaceuticals Ltd (ASX: PAR) today provided an update on the progress of its two phase 2 clinical trials confirming that commercially valuable phase 2 randomised double-blind placebo-controlled data is expected to read-out in Q4 CY 2018.

Phase 2b - Osteoarthritis / Bone Marrow Lesions – Update

A phase 2b, randomised double-blind placebo-controlled multicentre clinical trial to evaluate the effects of injectable pentosan polysulfate sodium (PPS) on pain in participants with knee osteoarthritis and concurrent subchondral bone marrow lesions (n=100).

Recruitment Status

- Trial is ahead of schedule, with 50 (50%) of participants recruited to date
- All five sites are operational and recruitment is proceeding ahead of schedule
- A sixth, experienced clinical trial site has also been initiated in Brisbane, QLD
- Interest in the clinical trial is very high from people with osteoarthritis

Paradigm is very pleased with the strong momentum that the clinical trial has been able to maintain. Injectable PPS has the potential to be a 'break-through' in the treatment of osteoarthritis (OA) where BMLs are present, whereas current therapies provide often inadequate pain-relief, have no effect on the degenerating joint structures or BMLs, and are also associated with "significant adverse side effects"¹.

¹ Seghal N, Colson J and Smith H; Expert Rev Neurother. 2013;13(11):1201-1220

It is estimated that the therapeutic treatment market size for OA is US\$5 billion per annum and this figure could potentially be multiples higher if new, effective, patented treatments such as PPS are commercialised.

OA also remains the most common form of joint disease globally. In the US alone, it affects over 27 million adults, while in Australia, arthritis affects around 3 million people. In both countries, the condition is a leading cause of pain and disability among the elderly and a cause of life-years lost due to disability².

The results from the osteoarthritis phase 2b clinical trial are expected in Q4 CY2018.

Phase 2a - Viral Arthralgia – Ross River Virus - Update

Phase 2a, randomised, double-blinded placebo-controlled pilot clinical trial treating a total of 24 participants across five trial sites in Victoria and Queensland. Patients with Ross River virus (RRV) induced arthralgia (painful joints) are being evaluated for safety, tolerability and effects on disease symptoms of PPS subcutaneous injections.

Recruitment Status

- The clinical trial is currently over 70% recruited
- Recruitment has slowed over the past 5 months due to the changeable prevalence of the disease, which is spread by mosquitos.
- A recent RRV outbreak on the Sunshine Coast, Qld is likely to increase the number of clinical trial participants.
- Paradigm has initiated an additional clinical trial site in the Sunshine Coast where reported RRV infections were high in the second half of 2017 and in to 2018.

Paradigm remains confident that the trial will recruit fully, and will complete within budget. Results from the pilot study are expected to provide important safety data, and efficacy signals will be evaluated to design subsequent larger trials. Paradigm hopes that the phase 2a trial will demonstrate the potential of PPS as an effective treatment for patients with persistent joint symptoms following Ross River virus infection, where a treatment is desperately needed.

Looking forward it is hoped that positive results from the RRV Phase 2a trial will provide the foundation for a commercial opportunity not only on RRV within the Australasian region but also for Chikungunya virus, potentially with the United States Department of Defense.

The results from this viral arthralgia phase 2a clinical trial are expected in Q3 CY2018.

TGA Special Access Scheme – Osteoarthritis patients treated - Update

Paradigm has provided PPS to doctors requesting to treat a total of 147 OA patients via the TGA Special Access Scheme. The osteoarthritis pain in these 147 patients failed to respond to a variety of other therapeutic, biologic and surgical treatments. Currently 45 out of the 147 patients have completed PPS treatment for their OA. The 45 OA patients treated with PPS demonstrated a clinical meaningful response with an average of 50% reduction in pain scores showing a high level of statistical significance of $p < 0.0001$. Paradigm will report on the remaining patients when PPS treatments are completed.

Mr. Rennie, Paradigm's CEO said "the clinical trials are aimed at diseases for which there are very few safe and effective drugs meaning Paradigm is focusing on market sectors where there are high levels of unmet medical needs and high levels of commercial interest. Investors will also note that the completion of phase 2 clinical trials are major value inflection points. I am very pleased to report to the Paradigm shareholders that we are ahead of schedule with our phase 2 osteoarthritis clinical trial".

ENQUIRIES:

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